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10/048,035	06/11/2002	Wolf Bertling	10848-017001	1180

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EXAMINER	
BAUSCH, SARAE L	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 06/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/048,035	BERTLING ET AL.	
	Examiner	Art Unit	
	Sarae Bausch	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 March 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

S.00'

DETAILED ACTION

1. Currently, claims 1-27 are pending in the instant application. Claim 28 has been canceled. All the amendments and arguments have been thoroughly reviewed but were found insufficient to place the instantly examined claims in condition for allowance. The following rejections are either newly presented, as necessitated by amendment, or are reiterated from the previous office action. Response to arguments follow. This action is FINAL.

Withdrawn Rejections

2. The rejection to claim 17, under 35 U.S.C. 112, second paragraph, made in section 5, page 3 of the previous office action, is withdrawn in view of the arguments made on page 5 of the response mailed 03/21/2004. The arguments were found persuasive and the rejection has been withdrawn.

3. The rejections of claims 1 and 27, under 35 U.S.C. 112, second paragraph, made in section 5, page 3 of the previous office action, is withdrawn in view of the amendment to the claims.

New Grounds of Rejections

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 1 and 27 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 is drawn to a method for labeling and identifying a solid, liquid, and gaseous substance. However, the final process step recites detecting whether or not

hybridization occurs wherein whether or not hybridization occurs identifies substance (S1-n). Accordingly, it is unclear as to whether positive hybridization would be associated with identification of substance (S1-n) or if no hybridization would be associated with identification of substance (S1-n).

New Grounds of Rejections

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-4, 6, 8-9, 12-13, 20, 24, 26 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Sano et al. (US Patent 5665539, Sept. 1997). Sano et al. teach a method of immuno-polymerase chain reaction in which a biotinylated nucleic acid molecule is used as a marker.

With regards to claims 1, 8, 9, 12, and 27, Sano et al. teach a method of making a chimera-pUC19 conjugate by mixing a purified chimera, streptavidin protein A chimera, and a biotinylated puc19 (instant claim 8 and 9) which results in four biotinylated pUC19 per chimera (first group of predefined nucleic acid molecules) (instant claim 12) (see column 11, lines 3-18). Sano et al. teach the method of adding the chimera-pUC19 (selecting at least one nucleic acid and contacting the substance with one predefined nucleic acid thereby labeling the substance) conjugate to each microtiter well and subjecting the mixture to PCR (see column 11, lines 4-12). Sano et al. teach using PCR amplification of the bla gene by using two 30-mer primers, bla-1 and

bla-2 that hybridized to a segment of the bla gene (providing a second group of nucleic acid, wherein the second group of nucleic acid comprises a detection sequence section (bla-1 and bla-2) complementary to one of the identification sequences (bla gene) and detect hybridization (PCR) and hybridization identifies the substance) (see column 12, lines 1-10).

With regard to claims 2-4, 6, and 24, Sano et al. teach using PCR amplification (instant claim 6 and 26) to generate a 261 bp fragment of the bla gene using bla-1 and bla-2 primers (identification sequence section located between two primer binding sections, comprising two complementary identification sequence sections (double stranded DNA)) (see column 12, lines 9-10 and figure 1).

With regard to claim 13, Sano et al. teach a method of conjugating a biotinylated pUC19 to a streptavidin-protein A chimera and adding to a microtiter well followed by subjecting the reaction to PCR (predefined nucleic acid molecules are bound to particles) (see column 11, lines 3-11).

With regard to claim 20, Sano et al. teach the method of synthesizing PCR primers by β-cyanoethyl phosphoramide chemistry using an automated DNA synthesizer (second group of nucleic acid molecules prepared synthetically) (see column 6, lines 11-14).

With regard to claim 26, Sano et al. teach primers that hybridize to a segment of the bla gene and generate a 261 bp fragment (identification sequence sections comprise primer binding sequence sections) (see column 6, lines 22-24).

8. Claims 1-11, 13-15, 20, 24, 26, and 27 are rejected under 35 U.S.C. 102(b) as

being anticipated by Slater et al. (WO 94/04918 March 1994). Slater et al. teach a method of detecting the liquid that has been marked by a nucleic acid tag.

With regard to claim 1 and 27, Slater et al. teach the method of tagging substances with a taggant (see page 24, lines 6-8), that can either be a naturally occurring or synthetic nucleic acids (contacting the substance with at least one predefined nucleic acid molecule thereby labeling the substance) (see page 24, lines 32-36) that are capable of forming duplexes with PCR primers and function as a template for polymerases used in PCR (see page 25, lines 22-25). Slater et al. teach a taggant DNA that is 70-90 base pairs with 30 nucleotides on either end constant to carry pre-determined sequences which recognize appropriate complementary primers for PCR amplification and DNA sequencing and middle region is variable with a unique, characteristic signal (nucleic acid molecule from a group of predefined nucleic acid molecules wherein the each predefined nucleic acid molecule comprises an identification sequence section) (see page 27, lines 2-23). Slater et al. teach detecting the nucleic acid by PCR (detecting hybridization and identifying substance) using primer G-18 and primer G-19 (providing a second group of nucleic acid molecules which comprise a detection sequence section complementary to one of the identification sequence sections) (see page 27, lines 28-32 and page 28, lines 4-7).

With regard to claim 2-4, Slater et al. teach a taggant double stranded DNA with two regions that carry pre-determined sequences that recognize appropriate complementary primers and middle region of DNA that is variable for a unique characteristic signal (identification sequence located between two primer binding sections, identification sequence contains two identification sequence sections complementary to each other) (see page 27, lines 11-19).

With regard to claim 5, Slater et al. teach primer G-18, which is the exact complement of the primer binding site and the complement primer G-19, which is the exact complement of the second primer binding site. The primers have the same melting point since each primer is the exact complement of the primer binding site (see page 27, lines 28-31 and page 28, lines 4-7).

With regard to claim 6 and 24, Slater et al. teach detection of nucleic acid by PCR (amplification) (see page 27, line 15-16, and page 28, lines 12-17).

With regard to claim 7-9, Slater et al. teach a biotin CPG attached to the 3' end of the taggant (biotin coupling group) (see page 27, line 20-22 and page 28, lines 8-12). The 3' end of the taggant is attached to an agent, biotin, that counteracts degradation by an exonuclease by protecting the 3' end of the nucleic acid.

With regard to claim 10 and 11, Slater et al. teach labeling the nucleoside base of the DNA with a hydrophobic hapten, such as fluorescein (fluorophoric group bound to predefined nucleic acid molecule and hapten coupling group labeled with fluorophoric group) (see page 31, lines 4-6).

With regard to claim 13, Slater et al. teach a taggant (predefined nucleic acid molecule) labeled with biotin to couple taggant to microbeads coated with streptavidin (see page 27, lines 20-23 and page 28, lines 8-11).

With regard to claim 14-15, Slater et al. teach a taggant (predefined nucleic acid molecule) attached to paramagnetic carboxyl-modified polystyrene beads (see page 29, lines 24-29) with a typical size of .1 to 1μm (see page 29, lines 18-20).

With regard to claim 20, Slater et al. teach a taggant (predefined nucleic acid molecule) that is a synthetic double stranded DNA sequence of 70 to 90 base pairs (see page 27, lines 3-5).

9. Claims 1, 7-10, 13, 15, 17, 18, 20-23, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Cantor et al (US Patent 5795714 Aug 1998).

Cantor et al. teach a method of replicating a probe array to screen biological samples for specific target sequences.

With regard to claim 1 and 27, Cantor et al. teach synthesizing one or more sets of nucleic acid probes simultaneously on a solid support (contacting (labeling) the substance (solid support) with at least one predefined nucleic acid molecule) (see column 8, lines 37-40). Cantor et al. teach a method comprising creating a set of nucleic acid probes (first group of predefined nucleic acid molecules), wherein each probe has a double stranded portion, a single stranded portion, and a random sequence within the singe stranded portion (selecting at least one nucleic acid molecule) which is hybridized to a nucleic acid target (providing a second group of nucleic acid molecules with a detection sequence and contacting the substance (first group of predefined nucleic acid molecules attached to a solid support) with the nucleic acid molecules provided from the second group under predefined hybridization conditions) to the set of nucleic acid probes and determining the nucleotide sequence of the target which hybridized to the single stranded portion of any probe (detecting hybridization wherein hybridization identifies the substance) (see column 7, lines 11-20).

With regard to claim 7-9, Cantor et al. teach attaching the nucleic acid probe to a solid support by immobilized 5'-labeled biotinylated DNA strands (coupling group, biotin) that consists of a variable 5 or 6 base segment plus the constant 15 base segment (see column 21,

lines 59-66). The 5' labeled biotinylated DNA strand counteracts degradation caused by an exonuclease by protecting the 5' to exposure to the exonuclease.

With regard to claim 10, Cantor et al. teach the probe or the array of probes labeled with a fluorescent chemical (see column 9, lines 4-6 and lines 20-26).

With regard to claim 13 and 15, Cantor et al. teach one 5' end biotinylated strand of the probe duplex (predefined nucleic acid molecule) is attached to a solid surface (see column 19, lines 34-40) and teach moderately dense arrays can be made using a typical X-Y robot to spot the biotinylated compounds individually (predefined nucleic acid molecules) onto a streptavidin coated surface (particle) and streptavidin-coated beads can be adhered, permanently to plastics like polystyrene (instant claim 15) (see column 20, lines 65-67, column 21 lines 1-9).

With regard to claim 17, Cantor et al. teach biotinylated double stranded probes (first nucleic acid group) attached to streptavidin coated beads adhered to polystyrene surface by spotting biotinylated compounds individually onto the streptavidin coated surface (predefined sites on substance, solid support) followed by hybridization of the target sequence to the probe by annealing and ligating the target sequence to the probe attached to the polystyrene beads (see column 20, lines 66-67, column 21, lines 1-8 and see column 31, lines 53-67) (second group of nucleic acid molecules bound to a predefined site on a solid surface).

With regard to claim 18, Cantor et al. teach a labeled probe or target molecule with a fluorescent chemical that may be directly or indirectly detected using scintillation fluid or a PhosphorImager, chromatic or fluorescent labeling or mass spectrometry (see column 9, lines 4-7 and lines 14-26) (complementary detection sequence detected by means of fluorescence).

With regard to claim 20, Cantor et al. teach the nucleic acids may be artificially synthesized (see column 6, lines 43-47).

With regard to claim 21 and 22, Cantor et al. teach the set of nucleic acid probes (first group of nucleic acid molecules) and target nucleic acid (second group of nucleic acid molecules) comprise PNA (nucleic acid analog) (see column 7, lines 20-24).

With regard to claim 23, Cantor et al. teach a target nucleic acid hybridized to a probed attached to a solid support, such as plastic, ceramic, metal, resin, film or other polymer, gel, membrane, or two or three dimensional array such as a chip or microchip (see column 12, lines 56-67).

10. Claims 1,2, 6, 16, 18, 24 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Bumstead et al. (J. Virological Methods 65 (1997) 75-81). Bumstead et al. teach a quantitative assay to determine the number of viral genomes present in samples by PCR amplification of the viral genome using fluorescent-tagged primers (abstract).

With regard to claim 1, Bumstead et al. teach 2μl cells (first group of predefined nucleic acid molecules) in a volume of 25ml PCR reaction (substance, thereby labeling substance) with 10pmol of primer (second group of nucleic acid molecules, wherein each nucleic acid molecule comprises a detection sequence section complementary to one of the identification sequences and contacting the substance with the nucleic acid molecules under predefined hybridization conditions). Bumstead et al. teach primers used to detect MDV to amplify a product of 279 bp (identification sequence of the predefined nucleic acid molecules). Bumstead et al. teach amplification of the PCR reaction and quantification of products of PCR by electrophoresis on a sequencer (detecting hybridization and identifying the substance). (see section 2.2 page 76-77).

With regard to claim 2, Bumstead et al. teach primers used to amplify a product of 279 bp (identification sequence located between two primer binding sequence sections). (see section 2.2 page 76)

With regard to claim 6 and 24 , Bumstead et al. teach amplification of product 279 of MDV by two primers by PCR. (see section 2.2 page 76-77)

With regard to claim 16, Bumstead et al. teach amplification of Marek's disease virus (particle), a herpes virus (abstract), from cells by PCR. The cells contain MDV and were not purified. The MDV contains the 279 bp region of the MDV genome. Bumstead teaches a particle (MVD virus) that is a virus-like particle included in the predefined nucleic acid molecule (MVD genome) (1st paragraph, 2nd column, page 76 and section 2.2, page 76-77).

With regard to claim 18, Bumstead et al. teach quantification of the fluorescent bands from the PCR products by ABI Genescna software (detection by fluorescence of the hybridization of the identification sequence section with the complementary detection sequence section) (see 1st paragraph, 1st column, page 77).

With regard to claim 25, Bumstead et al. teach the use of fluorescently labeled primer, primer 1 (1st paragraph, section2.2, page 76).

Response to Arguments

11. The response traverses the rejections under 35 U.S.C. 102 on page 6-7 of the response mailed 03/21/2005. The response asserts on page 7, first paragraph of the response that the cited references all require PCR amplification for detection and the claimed methods differ from the cited references because the claimed methods do not recite or require amplification, the N1-n and N'1-n nucleic acid molecules are not equivalent primers nor are IDS1-n and IDP1-n sequence

sections contained within the N1-n and N'1-n molecules and the detection of the labeled substance is dependent upon whether or not the various IDS1-n and IDP1-n sequence sections hybridize with one another and is not dependent upon their hybridization to and amplification of template DNA as the cited references teach. This response has been thoroughly reviewed but not found persuasive because the cited references do teach a method of amplification that comprises hybridization and although the claims do not recite or require amplification the method claims are broadly drawn to any type of hybridization, which encompasses amplification. The claims are not drawn to a method of hybridization and labeling that is restricted to hybridization without an amplification.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the N1-n and N'1-n nucleic acid molecules are not equivalent primers) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The claims do not require that N1-n or N'1-n nucleic acid molecules are different primers and therefore the cited references do teach the claimed method of labeling and identifying a solid, liquid or gaseous substance.

The response traverses on page 7, first paragraph, that IDS1-n and IDP1-n sequence sections are not contained within the N1-n and N'1-n molecules, respectively. This response has been thoroughly reviewed but not found persuasive because the claims require that the first group of nucleic acid molecules, N1-n comprise an identification sequence section (IDS1-n) and the second group of nucleic acid molecules, N'1-n comprise a detection sequence section (IDP1-

n) (instant claim 1 and 27) and therefore IDS-1 and IDP1-n is contained within the N1-n and N'1-n molecules. The response further asserts that the detection of the labeled substance is dependent upon whether or not the various IDS1-n and IDP1-n sequence sections hybridize with one another and is not dependent upon their hybridization to and amplification of template DNA. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the detection of the labeled substance is dependent upon whether or not the various IDS1-n and IDP1-n sequence sections hybridize with one another and is not dependent upon their hybridization to and amplification of template DNA) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The claims do not require a method of detection of a labeled substance by detecting hybridization of IDS1-n and IDP1-n sequence sections with one another. Therefore, the cited references do teach the claimed method of labeling and identifying a solid, liquid or gaseous substance by selecting at least one nucleic acid and contacting the substance with one predefined nucleic acid thereby labeling the substance, providing a second group of nucleic acid, wherein the second group of nucleic acid comprises a detection sequence section complementary to one of the identification sequences and detecting hybridization (PCR) thereby identifying the substance.

The response asserts on page 7, second paragraph, that the cited references do not teach or suggest a method for labeling and identifying a substance using the method steps recited in the pending claims. The response further asserts that according to the present invention, nucleic acids having a random sequence would not be used in the claimed methods and random sequence

nucleic acids would not allow for the identification of a substance as the pending claims recite. The response asserts that enzymatic extension does not take place from N1-n, N'1-n, IDS1-n, and IDP1-n and the claimed invention allows for complex labels to be detected. This response has been thoroughly reviewed but not found persuasive. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., random sequence would not allow for the identification of a substance or that enzymatic extension does not take place form N1-n, N'1-n, IDS1-n and IDP1-n) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The claims do not require a method of detection of a labeled substance by not using random sequence nucleic acids. The claims recite a method comprising selecting at least one nucleic acid molecule from a first group of predefined nucleic acid molecules and does not require any limitations to the type of sequence (random or known) of the nucleic acid. Furthermore, the claims do not limit that enzymatic extension does not take place from N1-n, N'1-n, IDS1-n and IDP1-n. Therefore, the cited references do teach the claimed method of labeling and identifying a solid, liquid or gaseous substance by selecting at least one nucleic acid and contacting the substance with one predefined nucleic acid thereby labeling the substance, providing a second group of nucleic acid, wherein the second group of nucleic acid comprises a detection sequence section complementary to one of the identification sequences and detecting hybridization (PCR) thereby identifying the substance.

Conclusion

12. No claims are allowable.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarae Bausch whose telephone number is (571) 272-2912. The examiner can normally be reached on M-F 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

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JEHANNE SITTON
PRIMARY EXAMINER

Sarae Bausch
Examiner
Art Unit 1634